·	Application No.	Applicant(s)
	09/424,815	NIBBERING ET AL.
Notice of Allowability	Examiner	Art Unit
	Sheridan K Snedden	1653
The MAILING DATE of this communication appearance and claims being allowable, PROSECUTION ON THE MERITS IS nerewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIP of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this apport or other appropriate communication IGHTS. This application is subject to	plication. If not included will be mailed in due course. THIS
1. 🔯 This communication is responsive to		
2. The allowed claim(s) is/are <u>28-34,41-43,45-47,49,55 and 60</u> .		
3. 🔀 The drawings filed on 11/29/1999 and 2/7/02 are accepted by the Examiner.		
4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some* c) None of the:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).  * Certified copies not received:  Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.  5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.  6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.  (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  1) hereto or 2) to Paper No./Mail Date  (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date  Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).		
7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.		
Attachment(s)		
1. Notice of References Cited (PTO-892)		Patent Application (PTO-152)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)	<ol> <li>Interview Summary Paper No./Mail Da</li> </ol>	te
<ul> <li>Information Disclosure Statements (PTO-1449 or PTO/SB/0</li> <li>Paper No./Mail Date</li> </ul>		
Examiner's Comment Regarding Requirement for Deposit  of Riclardial Material	8.	ent of Reasons for Allowance
of Biological Material	9. 🔲 Oulei	

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## **EXAMINER'S AMENDMENT**

- 1. This Office Action is in response to Paper filed 26 January 2004. Claims 1-27, 35-40, 44, 48, 50-54, 56-59 have been canceled. Applicant's amendment of claims 28-34, 41-43, 45-47, 49, 60 is acknowledged. Claims 28-34, 41-43, 45-47, 49, 55 and 60 are under examination.
- 2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gwen Wood on March 15, 2004.

- 3. Claims 28, 31, 32, 33, 41, 46, 49, 60 have been amended as follows:
- 28. (currently amended): Peptide fragment derived from ubiquicidine <u>having antimicrobial</u> <u>activity</u> and comprising a continuous series of between 6 to 18 amino acids from the amino acid sequence of ubiquicidine:

KVHGSLARAGKVRGQTPKVAKQEKKKKKTGRAKRRMQYNRRFVNVVPTFGKKKGPN ANS, (SEQ ID NO: 1) which does not include peptides having the amino acid sequence KVHGSLARAGKVRGQTPKVAKQ (SEQ ID NO: 10) or AGKVRGQTPKVAKQEKKKKKT (SEQ ID NO: 11).

31. (currently amended): Derivative of ubiquicidine or of a peptide fragment derived from ubiquicidine <u>having antimicrobial activity</u> and comprising a continuous series of between 6 to 18 amino acids from the amino acid sequence of ubiquicidine:

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KVHGSLARAGKVRGQTPKVAKQEKKKKKTGRAKRRMQYNRRFVNVVPTFGKKKGPNA NS, (SEQ ID NO: 1) which derivative has an amino acid sequence which is at least partly the

reverse of the amino acid sequence of the corresponding original peptide.

32. (currently amended): Derivative of a ubiquicidine or of a peptide fragment derived from

ubiquicidine having antimicrobial activity and comprising a continuous series of between 6 to 18

amino acids from the amino acid sequence of ubiquicidine:

KVHGSLARAGKVRGQTPKVAKQEKKKKKTGRAKRRMQYNRRFVNVVPTFGKKKGPNA

NS, (SEQ ID NO: 1) wherein at least one of the amino acids from the original peptide is replaced

by a stereoisomer of that amino acid.

33. (currently amended) Derivative of ubiquicidine or of a peptide fragment derived from

ubiquicidine having antimicrobial activity and comprising a continuous series of between 6 to 18

amino acids from the amino acid sequence of ubiquicidine:

KVHGSLARAGKVRGQTPKVAKQEKKKKKTGRAKRRMQYNRRFVNVVPTFGKKKGPNA

NS, (SEQ ID NO: 1) wherein the original amino acid chain is extended at one or both ends thereof

with one or more groups, such as D-amino acids, protecting against degradation.

41. (currently amended): A method for the therapy of an infection in humans and animals,

comprising:

a) administering an antimicrobial compound having antimicrobial activity

selected from the group consisting of ubiquicidine, a derivative of ubiquicidine, and a peptide

fragment derived from ubiquicidine and comprising a continuous series of between 6 to 18

amino acids from the amino acid sequence of ubiquicidine:

KVHGSLARAGKVRGQTPKVAKQEKKKKKTGRAKRRMQYNRRFVNVVP

TFGKKKGPNANS (SEQ ID NO: 1); and

b) treating the infection, wherein the antimicrobial action of the compound results

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in inhibiting or otherwise exerting a negative effect on the infection.

46. (currently amended): Antimicrobial agent, comprising at least a suitable quantity of one or more active components chosen from ubiquicidine; and/or peptide fragments derived from ubiquicidine, said ubiquicidine and/or said peptide fragments derived from ubiquicidine having antimicrobial activity, and comprising a continuous series of between 6 to 18 amino acids from the amino acid sequence of ubiquicidine:

KVHGSLARAGKVRGQTPKVAKQEKKKKKTGRAKRRMQYNRRFVNVVPTFGKKKGPN ANS (SEQ ID NO: 1).

49. (currently amended): Method for monitoring a treatment, comprising:

a) administering an antimicrobial agent <u>having antimicrobial activity</u>, comprising at least a suitable quantity of one or more active components chosen from ubiquicidine, peptide fragments derived from ubiquicidine and comprising a continuous series of between 6 to 18 amino acids from the amino acid sequence of ubiquicidine:

KVHGSLARAGKVRGQTPKVAKQEKKKKKTGRAKRRMQYNRRFVNVVP TFGKKKGPNANS (SEQ ID NO: 1),

- b) observing the localization of the agent in time, and
- c) following the effect of the treatment, wherein the antimicrobial action of the compound results in inhibiting or otherwise exerting a negative effect on the infection.
- 60. (currently amended): Method for providing prophylactic action against an infection in humans or animals, comprising:
- a) administering a peptide fragment, derived from ubiquicidine <u>having</u> antimicrobial activity and comprising a continuous series of between 6 to 18 amino acids from the amino acid sequence of ubiquicidine:

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KVHGSLARAGKVRGQTPKVAKQEKKKKKTGRAKRRMQYNRRFVNVVP TFGKKKGPNANS, (SEQ ID NO: 1) which does not include peptides having the amino acid sequence KVHGSLARAGKVRGQTPKVAKQ (SEQ ID NO: 10) or AGKVRGQTPKVAKQEKKKKKT (SEQ ID NO: 11) in the form of a coating, wherein said administration results in preventing the infection.

## Conclusion

4. Claims 28-34, 41-43, 45-47, 49, 55 and 60 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS

March 15, 2004

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KAREN COCHRANE CARLSON, PH.D PRIMARY EXAMINER

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